

AMENDMENTS TO THE CLAIMS

Claims 1, 3-12 and 14-33 are presently pending in this application. Claims 2 and 13 are cancelled herein without prejudice or disclaimed. New claim 33 is added herein.

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently amended) A hydrostatic delivery system comprising a hydrostatic couple and an agent of interest, said hydrostatic couple comprising one or more than one hydrodynamic fluid-imbibing polymer, and one or more than one hydrostatic pressure-modulating agent, said hydrostatic pressure-modulating agent comprising a hydrophilic cross-linked polymer, and wherein said agent of interest is released at a rate that is substantially concentration independent.

Claim 2 (canceled)

3. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, wherein said hydrodynamic fluid-imbibing polymer is a cross-linked polymer having a swell capacity in a fluid environment of between about 1 weight % to about 3000 weight %.

4. (Original) The hydrostatic delivery system according to claim 3, wherein said cross-linked polymer is present from about 4 weight % to about 96 weight % of the total formulation.

5. (Currently amended) The hydrostatic delivery system according to claim [[2]] 1, wherein said hydrostatic pressure modulating agent is a cross-linked, rapidly swelling polymer having a swell capacity in a fluid environment of between about 0.5 weight % to about 500 weight %.

6. (Currently amended) The hydrostatic delivery system according to claim 5, wherein said cross-linked rapidly swelling polymer is present from about 0.5 weight % to about 50 weight % of the total formulation.

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7. (Currently amended) The hydrostatic delivery system according to claim [[2]] 1, wherein said hydrostatic pressure modulating agent [[,]] further comprises an expansion source.

8. (Original) The hydrostatic delivery system according to claim 7, wherein said expansion source is selected from the group consisting of a carbon-dioxide precursor, an oxygen precursor, and a chlorine dioxide precursor.

9. (Currently amended) The hydrostatic delivery system according to claim 3, wherein said hydrodynamic fluid-imbibing polymer and said hydrostatic pressure modulating agent are present at a ratio from about 99:1 to about 50:50 by weight.

10. (Currently amended) The hydrostatic delivery system according to claim 3, wherein:

~~said hydrodynamic polymer is~~ hydrostatic pressure modulating agent further comprises an expansion source selected from the group consisting of a carbon dioxide precursor, an oxygen precursor or, and a chlorine dioxide precursor; and [[,]]

said hydrodynamic fluid-imbibing polymer and said hydrostatic pressure modulating agent are present in a ratio from about 99:1 to about 70:30 by weight.

11. (Previously presented) The hydrostatic delivery system according to claim 1 wherein the agent of interest comprises a plurality of discrete active particulates.

12. (Currently amended) The hydrostatic delivery system according to claim [[2]] 1, wherein:

said hydrodynamic fluid-imbibing polymer comprises one or more of the compounds selected from the group consisting of:

- i) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;

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- ii) one or more starch derivatives cross-linked by epichlorhydrin
Epichlorhydrin, ~~Phosphorous~~ phosphorous oxychloride (POCl_3), or ~~Sodium~~
sodium trimetaphosphate;
 - iii) a crosslinked polyglucan;
 - iv) a crosslinked polyacrylate resin;
 - v) a crosslinked polyethylenimine;
 - vi) a crosslinked polyallylamine, and
~~combinations~~ a combination thereof; and
- wherein the hydrostatic pressure modulating agent comprises one or more
of the compounds selected from the group consisting of:
- a) a homopolymer of cross-linked N-vinyl-2-pyrrolidone;
 - b) a rapidly expanding cross-linked cellulose derivative; and
a combination thereof

Claim 13 (cancelled)

14. (Currently amended) The hydrostatic delivery system according to claim [[12]] 1, wherein said acrylic-acid polymer is an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol ~~selected from a group consisting of Carbopol.RTM.971P, Carbopol.RTM.934P, Carbopol.RTM.971P, Carbopol.RTM. EX507, and a combination thereof.~~

15. (Original) The hydrostatic delivery system according to claim 14, wherein said acrylic-acid polymer has a viscosity from about 3,000 centipoise to about 45,000 centipoise at 0.5% w/w concentration in water at 25°C.

16. (Original) The hydrostatic delivery system according to claim 15, wherein said acrylic-acid polymer has a primary particle size range from about 3.00 to about 10.00 microns in diameter.

17. (Currently amended) The hydrostatic delivery system according to claim [[12]] 1, wherein said ~~polyglycan~~ polyglucan is selected from the group consisting of amylose, dextran, ~~pullman~~ pullulan succinate containing diester or diether crosslinks, ~~pullman~~ pullulan glutarates containing diester or diether crosslinks, and a combination thereof.

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18. (Currently amended) The hydrostatic delivery system according to claim [[13]] 1, wherein said hydrostatic pressure modulating agent comprises a homopolymers homopolymer of cross-linked N-vinyl-2-pyrrolidone ~~are selected from the group consisting of Polyplasdene.RTM.XL, Polyplasdene.RTM. XL-10, Polyplasdene.RTM. INF-10, and a combination thereof.~~

19. (Original) The hydrostatic delivery system according to claim 16, wherein said cross-linked N-vinyl-2-pyrrolidone has a particle size from about 9 microns to about 150 microns.

20. (Currently amended) The hydrostatic delivery system according to claim [[13]] 1, wherein said rapidly swelling cross-linked cellulose derivative is selected from the group consisting of cross-linked carboxymethyl cellulose, sodium starch glycolate, and a combination thereof.

21. (Currently amended) The hydrostatic delivery system according to claim 8, wherein said carbon dioxide precursor is selected from the group consisting of carbonates, sesquicarbonate, ~~hydrogenearbonate~~ hydrogen carbonate, potassium carbonate, lithium carbonate, sodium carbonate, ammonium carbonate, sodium amino acid carbonate, sodium glycine carbonate, L-lysine carbonate and arginine carbonate.

22. (Original) The hydrostatic delivery system according to claim 8, wherein said oxygen precursor is selected from the group consisting of sodium percarbonate, sodium perborate monohydrate, anhydrous sodium perborate, effervescent perborate, and sodium dichloroisocyanurate.

23. (Original) The hydrostatic delivery system according to claim 8, wherein said chlorine dioxide precursor is selected from the group consisting of sodium hypochlorite and calcium hypochlorite.

24. (Currently amended) The hydrostatic delivery system according to claim [[2]] 1, wherein the dosage form is a multiparticulate matrix tablet, or capsule.

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25. (Currently amended) The hydrostatic delivery system according to claim [[2]] 1, further comprising an enteric coating or one or more pH sensitive barrier polymers.

26. (Currently amended) The hydrostatic delivery system according to claim 2, wherein the agent of interest is selected from the group consisting of analgesic, anti-inflammatory, antimicrobial, amoebicidal, trichomonocidal agents, anti-parkinson, anti-malarial, anticonvulsant, anti-depressants, antiarthritics, anti-fungal, antihypertensive, antipyretic, anti-parasite, antihistamine, alpha-~~adrenargic~~ adrenergic agonist, alpha blocker, anesthetic, bronchial dilator, biocide, bactericide, bacteriostat, beta adrenergic blocker, calcium channel blocker, cardiovascular drug, contraceptive, decongestants, diuretic, depressant, diagnostic, electrolyte, hypnotic, hormone, hyperglycemic, muscle relaxant, muscle contractant, ophthalmic, parasympathomimetic, psychic energizer, sedative, sympathomimetic, tranquilizer, urinary, vaginal, viricide, vitamin, non-steroidal anti-inflammatory, angiotensin converting enzyme inhibitors, polypeptide, proteins, and sleep inducers.

27. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, further comprising one or more pharmaceutical excipients including but not limited to viscosity enhancer(s), enteric polymer(s), pH-specific barrier polymer(s), diluent(s), anti-adherent(s), glidant(s), binder(s), solubilizer(s), channeling agent(s), wetting agent(s), buffering agent(s), flavorants, adsorbents, sweetening agent(s), colorant(s) and lubricant(s).

28. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, further comprising an adjuvant.

29. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, wherein said hydrostatic delivery system is a matrix-type solid compact, made by a compression or pelletization method.

30. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, wherein said hydrostatic delivery system is a matrix-type extrusion spheroid, made by a wet or dry extrusion method.

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31. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, wherein said hydrostatic delivery system is granulated or microencapsulated to form particulates that may be compressed into solid compacts or filled into capsules.

32. (Currently amended) The hydrostatic delivery system of claim [[2]] 1, wherein said hydrostatic delivery system is selected from the group consisting of granulated, particulate, spheroidal, compact, and dry blends, said hydrostatic delivery system can be filled into a capsule or suspended in a suitable liquid vehicle.

33. (New) A hydrostatic delivery system comprising a hydrostatic couple and an agent of interest, said hydrostatic couple comprising one or more than one hydrodynamic fluid-imbibing polymer, and one or more than one hydrostatic pressure modulating agent, said hydrodynamic fluid-imbibing polymer comprising one or more than one compound selected from the group consisting of:

- i) a crosslinked hydrodynamic polymer;
- ii) an acrylic-acid polymer cross-linked with allylsucrose or allylpentaerythritol;
- iii) one, or more than one starch derivative cross-linked by epichlorhydrin, phosphorous oxychloride (POCl_3), or sodium trimetaphosphate;
- iv) a crosslinked polyglucan;
- v) a crosslinked polyacrylate resin;
- vi) a crosslinked polyethylenimine;
- vii) a crosslinked polyallylamine, and
a combination thereof; and

said hydrostatic pressure modulating agent comprises one or more than one compound selected from the group consisting of:

- a) a homopolymer of cross-linked N-vinyl-2-pyrrolidone;
- b) a rapidly expanding cross-linked cellulose derivative; and
a combination thereof.